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35411	7590	03/16/2004	EXAMINER	
KILYK & BOWERSOX, P.L.L.C.			MUTSCHLER, BRIAN L	
3603 CHAIN BRIDGE ROAD			ART UNIT	
SUITE E			PAPER NUMBER	
FAIRFAX, VA 22030			1753	

DATE MAILED: 03/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/938,947

Applicant(s)

WOUDENBERG ET AL.

Examiner

Brian L. Mutschler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) 37-71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 August 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date see box 6.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: See Continuation Sheet.

Continuation of Attachment(s) 6). Other: IDS: 20011116; 20021233; 20030815.

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-36, drawn to a device with an electrochemical cell and polarity inverting device, classified in class 204, subclass 242.
  - II. Claims 37 and 38, drawn to a method of separating components, classified in class 204, subclass 450.
  - III. Claims 39 and 40, drawn to a method of influencing properties, classified in class 205, subclass 687.
  - IV. Claims 41 and 42, drawn to a method of preparing an electrode, classified in class 205, subclass 628.
  - V. Claims 43-51, drawn to a device for separating components having a channel and controller, classified in class 204, subclass 600.
  - VI. Claims 52-55, drawn to a method of separating components by changing positions using non-uniform flow, classified in class 204, subclass 450.
  - VII. Claims 56-59, drawn to a method of concentrating components to hold a position and concentrate components using uniform flow, classified in class 204, subclass 554.
  - VIII. Claims 60 and 61, drawn to a sample separation device having a pre-charged cell, classified in class 204, subclass 242.

- IX. Claims 62-65, drawn to a palladium anode and devices using the palladium anode, classified in class 204, subclass 280. This group is also subject to a species restriction.
- X. Claims 66-71, drawn to an analytical device having a flow pathway and pressure relief pathway, classified in class 204, subclass 242.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of Group I and Groups II and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus may be used to perform different processes, such as an electrolytic chemical reaction or simply for transport of a single compound.

3. Inventions of Group V and Groups VI and VII are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus can be used to perform a different process, such as performing an electrolytic reaction.

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4. Inventions of Group I, Group V, Group VIII, Group IX, Group X, Group XI, Group XII, and Group XIII are unrelated. Each of these inventions provides different structural limitations pertaining to uniquely defined devices. Each unique feature is identified above in the groupings.

5. Inventions of Group II, Group III, Group IV, Group VI, and Group VII are unrelated. These inventions recite different processes requiring different process steps.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

7. This application contains claims directed to the following patentably distinct species of the claimed invention: Claim 63, drawn to an electrochemical cell with a palladium anode, classified in class 204, subclass 242; Claim 64, drawn to a sample separation device with a palladium anode, classified in class 204, subclass 660; and Claim 65, drawn to an electrophoretic device with a palladium anode, classified in class 204, subclass 600.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 62 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims

readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. During a telephone conversation with Mr. Leonard Bowersox on February 6, 2004, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-36. Affirmation of this election must be made by applicant in replying to this Office action. Claims 37-71 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Comments***

10. The instant claims recite the phrase "bubble free electrode." The scope of the claims has been defined in terms of the meaning provided in the disclosure. The disclosure defines the phrase "bubble free electrodes" to "encompass different electrodes that produce no bubbles during operation" (see page 3, lines 21-23 of the instant disclosure). The disclosure further states, "while the use of stainless steel electrodes leads, after a very short time, to the formation of gas bubbles at those electrodes under conditions of electrolysis, the use of electrodes made of palladium, on the other hand, prevents the formation of such bubbles for a much longer period of time" (see page 50, lines 2-6). Therefore, the scope of the phrase "bubble free electrodes" encompasses any electrode capable of being operated for at least some period of time without producing bubbles.

### ***Drawings***

11. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description:

**810** and **812** (fig. 8b); **810** and **812**, which are also duplicative (fig. 9); and **110** (fig. 19).

A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

12. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character **810** has been used to designate both non-charged components(?) and an unidentified feature in figure 9. Reference character **812** has been used to designate both biomolecules(?) and an unidentified feature in figure 9. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

13. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: **802** (see page 33, line 22 and page 34, line 1) and **108'** (see page 48, line 8). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

14. It appears that the reference character **802** (page 33, line 22 and page 34, line 1) used in the specification should be changed to **812**. It also appears that the non-charged components of figure 9 (see page 34, line 3) should be identified by the reference character **810**.

***Specification***

15. The disclosure is objected to because of the following informalities:
- a. On page 16 at line 8, please provide the Application No. of the concurrently filed application.
  - b. On page 29 at line 13, please change "Fig. 7" to --Fig. 7a--.
  - c. On page 33 at line 22 and on page 34 at line 1, it appears that the reference character "**802**" should be changed to --**812**--.
  - d. On page 34 at line 3, it appears that the reference character --**810**-- should be inserted after "Non-charged components."

Appropriate correction is required.

***Claim Objections***

16. Claims 15, 19, and 31 are objected to because of the following informalities:
- a. In claim 15 at line 2, please change "connected said power source" to --connected to said power source--.
  - b. In claim 19 at line 1, please change "The analytical cell" to --The analytical device--.
  - c. In claim 31 at line 2, please delete "comprises".

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

17. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

18. Claims 15 and 31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of an alternating current power supply in an embodiment such as that shown in Figures 8a and 8b, which comprises electrodes **73** and **74** disposed on the lateral sides of a channel **71** and powered by an alternating current power source, does not reasonably provide enablement for a device having electrodes disposed in anodic and cathodic reservoirs, wherein the electrodes are connected to an alternating current power source. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The embodiment described in the specification does not appear to function in the same manner as the embodiment recited in the instant claims. The embodiment described in the disclosure that uses an alternating current power source provides a driving force to drive the electrodes, which are formed on the side of what would be equivalent to the connection means. The claims recite anodic and cathodic reservoirs containing the electrodes and having a connection between the reservoirs. Since the embodiments are disclosed as having different structures, it is not apparent how the alternating current power source would be used in the claimed embodiment and what the resulting structure comprises.

19. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

20. Claims 1-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "a power source having a positive terminal that is normally in electrical contact with said first electrode" in lines 13-14. This limitation is indefinite because the structure of the device is not positively recited. The term "normally" merely indicates one state in which the device can exist, but does not require the device to exist in that state. The term "normally" or "normal" should not be used in the claims. The terms appear in claim 1 at lines 13, 14 and 17 and in claim 20 at lines 11 and 12. The same applies to dependent claims 2-19 and 21-36.

Claims 2-4, 18, and 32 are indefinite because they fail to positively recite structural limitations. The claims recite process limitations that do not further limit the structure of the claimed device.

Claims 12 and 28 are recite the limitation "at least one of said first and second electrodes comprises a nickel-cadmium electrode system" in lines 1-2 of each claim. This limitation is indefinite because the resulting structure of the device is unclear. A single electrode is substituted with an entire system, which the specification defines on page 12 at line 20 as having two different electrodes. What is the structure of the resulting electrode? Is it a Cd, CdO, Ni(OH)<sub>4</sub>, Ni(OH)<sub>2</sub>, Ni, or another type of electrode,

such as a nickel cadmium alloy? It is assumed that the electrode may comprise any of the above listed electrodes.

Claim 32 recites "at least one of said first and second electrodes ... is connected to an alternating current power supply" in lines 1-2. This limitation is indefinite because it is missing essential structural relationship between the power source recited in claim 20 and the alternating current power supply recited in claim 32. Are the power source and power supply the same power source or are they different power sources?

### ***Claim Rejections - 35 USC § 102***

21. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

22. Claims 1-7, 16-23, and 32-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Bjornson et al. (U.S. Pat. No. 6,103,199).

Regarding claims 1, 20, and 34, Bjornson et al. disclose a capillary electroflow apparatus comprising an electrochemical cell having anodic and cathodic reservoirs **132** and **136**, wherein each reservoir has an electrode **130** and **134** made of a material such as palladium, which absorbs hydrogen and is capable of operating in a bubble-free

manner (fig. 4; col. 20, lines 18-32; col. 23, lines 48-59). A channel **122** connects the reservoirs (fig. 4). The device further comprises a power source to connect to the electrodes and means to invert the polarity of the electrodes (col. 22, lines 12-31).

Bjornson et al. also disclose a sample introduction port and reservoir **142** to introduce a sample into the device (fig. 4; col. 20, lines 18-32).

Regarding claims 2-4, 18, and 32, the device can be used to induce electrokinetic movement and can switch the polarity of the electrodes (col. 11, lines 55-60; col. 22, lines 12-31).

Regarding claims 5-7 and 21-23, Bjornson et al. disclose that the electrodes may comprise palladium (col. 23, lines 48-59).

Claims 16, 17, 35, and 36, the device is used to induce electroosmotic flow or electrophoretic flow (col. 11, lines 55-60).

Regarding claims 19 and 33, the power source can deliver fields of 10 to 1000 V/cm, which provides a voltage within the range recited in the claims (col. 22, lines 12-26).

Since Bjornson et al. teach all of the structural limitations recited in the instant claims, the reference is deemed to be anticipatory.

23. Claims 1-6, 13, 14, 16, 18, 20-23, 29, 30, 32, 34, and 35 are rejected under 35 U.S.C. 102(e) as being anticipated by Cabilly et al. (U.S. Pat. No. 6,379,516).

Regarding claims 1, 20, and 34, Cabilly et al. disclose an electrophoretic device comprising an electrochemical cell having anodic and cathodic reservoirs **120** and **122**

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for holding an electrolyte and electrodes, a connection between the two reservoirs, and a sample containment chamber **18** having an opening for introducing the sample into the chamber (fig. 9; col. 11, line 11 to col. 12, line 27). The device further comprises a power source **104** and conductive rods **24** and **26** or cables **105** and **107** capable of switching the polarity of the electrodes (fig. 16). The electrodes are bubble free electrodes (col. 11, lines 26-29).

Regarding claims 2-4, 18, and 32, the device has a structure capable of performing the intended use recited in the claims.

Regarding claims 5, 6, 21, and 22, the electrode is a palladium electrode that absorbs hydrogen (col. 11, lines 26-29).

Regarding claims 13, 14, 29, and 30, a second embodiment comprises ion exchange matrices and an electrolyte solution (fig. 4; col. 8, lines 44-60).

Regarding claims 16 and 35, the device is an electrophoretic device (col. 7, lines 46-48).

Since Cabilly et al. teach all of the structural limitations recited in the instant claims, the reference is deemed to be anticipatory.

### ***Claim Rejections - 35 USC § 103***

24. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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25. Claims 1-7, 16-23, and 32-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramsey (U.S. Pat. No. 6,001,229) in view of WO 00/74850, herein referred to as WO '850.

Regarding claims 1, 20, and 34, Ramsey discloses a microfluidic device comprising an electrochemical cell having anodic and cathodic reservoirs **32** and **36** with electrodes **40** and **44** disposed therein, a sample reservoir **30** for the injection of a sample, and a connection **54** between the reservoirs (fig. 1; col. 4, lines 32-53). The device further comprises a power source and a polarity switching device for switching the polarity of the electrodes (figs. 1 and 21a-21c; col. 4, lines 38-41; col. 15, lines 9-13).

Regarding claims 2-4, 18, and 32, the device is used to electrophoretically move samples and is capable of reversing the polarity (col. 5, lines 44-56; col. 15, lines 9-13).

Regarding claims 5 and 21, the electrodes are made of platinum (col. 4, lines 36-38).

Regarding claims 16, 17, 35, and 36, the device uses electroosmosis and electrophoresis (col. 2, lines 18-21).

Regarding claims 19 and 33, Ramsey disclose that the device is operated between 60 V/cm and 1,500 V/cm, which provides a voltage within the range recited in the claims (col. 8, lines 29-44).

The device of Ramsey differs from the instant invention because Ramsey does not disclose the following:

- a. At least one electrode is a bubble-free electrode, as recited in claims 1 and 20.
- b. At least one electrode comprises a palladium metal material, as recited in claims 6 and 22.
- c. Both electrodes comprise a palladium metal material, as recited in claims 7 and 23.

WO '850 teaches that gas bubbles interfere with uniform flow within microchannels, and teach the use of nongassing electrodes such as palladium and platinum electrodes (page 8, last paragraph; page 15, second paragraph).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the platinum electrode of Ramsey to use a bubble free palladium electrode as taught by WO '850 because gas bubbles interfere with the uniform flow of microchannels.

26. Claims 8-12 and 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cabilly et al. (U.S. Pat. No. 6,379,516), as applied above to claims 1-6, 13, 14, 16, 18, 20-23, 29, 30, 32, 34, and 35, and further in view of Yano et al. (U.S. Pat. No. 6,077,625).

Cabilly et al. teach the limitations recited in claims 1-6, 13, 14, 16, 18, 20-23, 29, 30, 32, 34, and 35 of the instant invention, as explained above in section 23. Cabilly et al. further teach that the electrode can be formed of any suitable material "capable of

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adsorbing gases produced during the electrophoretic separation process" (col. 11, lines 11-14 and 26-29).

The device of Cabilly et al. differs from the instant invention because Cabilly et al. do not teach the following:

- a. At least one or both electrodes include a nickel hydroxide material, as recited in claims 8, 10, 24, and 26.
- b. The nickel hydroxide compound is of the formula  $\text{Ni}(\text{OH})_x$ , where  $x$  is 2 or 4, as recited in claims 9, 11, 25, and 27.
- c. At least one electrode comprises a nickel-cadmium electrode system, as recited in claims 12 and 28.

Nickel hydroxide is a well-known material in the art of batteries and electrochemical sensors. For example, Yano et al. teach that nickel hydroxide electrodes absorb hydrogen gas (col. 2, lines 33-44; col. 8, lines 42-48).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the bubble free electrode of Cabilly et al. to use nickel hydroxide electrode as taught by Yano et al. because nickel hydroxide is a hydrogen-absorbing material and Cabilly et al. teach that any material capable of absorbing hydrogen can be used. Nickel hydroxide is a part of a nickel cadmium electrode system, as acknowledged by Applicant on page 14 of the instant disclosure.

**Conclusion**

27. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following references teach various gas-absorbing electrodes and systems using alternating current power supplies similar to the embodiment used disclosed in the instant disclosure.

U.S. Pat. No. 5,035,790 Morimoto et al.

U.S. Pat. No. 5,540,831 Klein

U.S. Pat. No. 5,624,539 Ewing et al.

U.S. Pat. No. 6,458,259 Parce et al.

U.S. Pat. No. 6,569,306 Read et al.

US 2002/0166592 A1 Liu et al.

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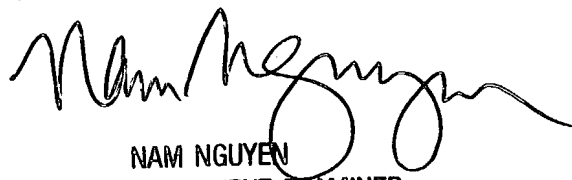
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian L. Mutschler whose telephone number is (571) 272-1341. The examiner can normally be reached on Monday-Friday from 7:30am to 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

blm  
February 11, 2004



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SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1700